

Applicant: Smith *et al.*

Due Date: None

Art Unit: 1623

Application No.: 09/845,157

Examiner: To be assigned

Filed: May 1, 2001

Docket: 0942.5040001

Atty: RWE/MTT

For: **Thermostable Reverse Transcriptases and Uses Thereof**

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. SKG&F Cover Letter (*in duplicate*);
2. Information Disclosure Statement (*in duplicate*);
3. List of references cited on Form PTO-1449 (15 sheets);
4. A copy of each reference cited on Form PTO-1449 (83 references); and
5. One (1) Return Postcard.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Smith *et al.*

Appl. No. 09/845,157

Filed: May 1, 2001

For: **Thermostable Reverse
Transcriptases and Uses Thereof**

Confirmation No. 2674

Art Unit: 1623

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Atty. Docket: 0942.5040001/RWE/MTT

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. A copy of each of these documents is provided.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications:

09/677,574, filed October 3, 2000;

09/808,124, filed March 15, 2001; and

09/902,741, filed July 12, 2001,

which are directed to related technical subject matter. Pursuant to 37 C.F.R. §1.98 (a) (2), legible copies of these applications are provided herein as documents AM15, AN15, and AO15, respectively. The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
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Date: Nov. 2, 2001

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

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U.S. PATENT DOCUMENTS

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| | AA1 | 5,244,797 | 09/14/1993 | Kotewicz <i>et al.</i> | 435 | 194 | 03/18/1991 |
| | AB1 | B1 5,244,797 | 08/25/1998 | Kotewicz <i>et al.</i> | 435 | 194 | 03/18/1991 |
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| | AE1 | 5,668,005 | 09/16/1997 | Kotewicz <i>et al.</i> | 435 | 194 | 03/12/1996 |
| | AF1 | 6,063,608 | 05/16/2000 | Kotewicz <i>et al.</i> | 435 | 194 | 02/10/1997 |
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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION |
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| | AI1 | WO 98/47912 | 10/29/1998 | WIPO | | | Yes No |
| | AJ1 | WO 99/10366 | 03/04/1999 | WIPO | | | Yes No |
| | AK | | | | | | Yes No |

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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| | AL | <u>1</u> | Arion, D., <i>et al.</i> , "The K65R Mutation Confers Increased DNA Polymerase Processivity to HIV-1 Reverse Transcriptase," <i>J. Biol. Chem.</i> 271:19860-19864, American Society for Biochemistry and Molecular Biology (1996) |
| | AM | <u>1</u> | Bakhanashvili, M., and Hizi, A., "The fidelity of the reverse transcriptases of human immunodeficiency viruses and murine leukemia virus, exhibited by the mispair extension frequencies, is sequence dependent and enzyme related," <i>FEBS</i> 319:201-205, Elsevier Science Publishers B.V. (1993) |
| | AN | <u>1</u> | Bakhanashvili, M., and Hizi, A., "A possible role for cysteine residues in the fidelity of DNA synthesis exhibited by the reverse transcriptases of human immunodeficiency viruses type 1 and type 2," <i>FEBS</i> 304:289-293, Elsevier Science Publishers B.V. (1992) |
| | AO | <u>1</u> | Bakhanashvili, M., <i>et al.</i> , "Mutational studies of human immunodeficiency virus type 1 reverse transcriptase: the involvement of residues 183 and 184 in the fidelity of DNA synthesis," <i>FEBS Lett.</i> 391:257-262, Elsevier Science Publishers B.V. (1996) |
| | AP | <u>1</u> | Bakhanashvili, M., and Hizi, A., "Fidelity of the RNA-Dependent DNA Synthesis Exhibited by the Reverse Transcriptases of Human Immunodeficiency Virus Types 1 and 2 and of Murine Leukemia Virus: Mismatch Extension Frequencies," <i>Biochem.</i> 31:9393-9398, American Chemical Society (1992) |

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| | AI | | | | | | Yes No |
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| | AL | 2 | Barnes, W.M., "The fidelity of <i>Taq</i> polymerase catalyzing PCR is improved by an N-terminal deletion," <i>Gene</i> 112:29-35, Elsevier Science Publishers B.V. (1992) |
| | AM | 2 | Basu, S., <i>et al.</i> , "sulphydryl groups in the template-primer-binding domain of murine leukemia virus reverse transcriptase," <i>Biochem. J.</i> 296:577-583, The Chemical Society, London (1993) |
| | AN | 2 | Bebenek, K., <i>et al.</i> , "Reduced Frameshift Fidelity and Processivity of HIV-1 Reverse Transcriptase Mutants Containing Alanine Substitutions in Helix H of the Thumb Subdomain," <i>J. Biol. Chem.</i> 270:19516-19523, American Society for Biochemistry and Molecular Biology (1995) |
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| | AL | <u>3</u> | Berger, S.L., <i>et al.</i> , "Reverse Transcriptase and Its Associated Ribonuclease H: Interplay of Two Enzyme Activities Controls the Yield of Single-Stranded Complementary Deoxyribonucleic Acid," <i>Biochemistry</i> 22:2365-2372, The American Chemical Society (1983) |
| | AM | <u>3</u> | Blain, S.W., and Goff, S.P., "Effects on DNA Synthesis and Translocation Caused by Mutations in the RNase H Domain of Moloney Murine Leukemia Virus Reverse Transcriptase," <i>J. Virol.</i> 69:4440-4452, The American Society for Microbiology (1995) |
| | AN | <u>3</u> | Caliendo, A.M., <i>et al.</i> , "Effects of Zidovudine-Selected Human Immunodeficiency Virus Type 1 Reverse Transcriptase Amino Acid Substitutions on Processive DNA Synthesis and Viral Replication," <i>J. Virol.</i> 70:2146-2153, The American Society for Microbiology (1996) |
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| | AP | <u>3</u> | Carter, P. and Wells, J.A., "Engineering Enzyme Specificity by 'Substrate-Assisted Catalysis,'" <i>Science</i> 237:394-399, American Association for the Advancement of Science (1987) |

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| | AL | <u>4</u> | Chen, Y., and Marion, P.L., "Amino Acids Essential for RNase H Activity of Hepadnaviruses Are Also Required for Efficient Elongation of Minus-Strand Viral DNA," <i>J. Virol.</i> 70:6151-6156, The American Society for Microbiology (1996) |
| | AM | <u>4</u> | Chowdhury, K., <i>et al.</i> , "Elucidation of the Role of Arg 110 of Murine Leukemia Virus Reverse Transcriptase in the Catalytic Mechanism: Biochemical Characterization of Its Mutant Enzymes," <i>Biochemistry</i> 35:16610-16620, American Chemical Society (1996) |
| | AN | <u>4</u> | Creighton, S., <i>et al.</i> , "Base Mismatch Extension Kinetics," <i>J. Biol. Chem.</i> 267:2633-2639, American Society for Biochemistry and Molecular Biology (1992) |
| | AO | <u>4</u> | DeStefano, J.J., <i>et al.</i> , "Parameters that influence processive synthesis and site-specific termination by human immunodeficiency virus reverse transcriptase on RNA and DNA templates," <i>Biochimica et Biophysica Acta</i> 1131:270-280, Elsevier Science Publishers B.V. (1992) |
| | AP | <u>4</u> | Diaz, L., and DeStefano, J.J., "Strand transfer is enhanced by mismatched nucleotide at the 3' primer terminus: a possible link between HIV reverse transcriptase fidelity and recombination," <i>Nucleic Acids Res.</i> 24:3086-3092, Oxford University Press (1996) |

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| | AL | <u>5</u> | Drosopoulos, W.C., and Prasad, V.R., "Increased Polymerase Fidelity of E89G, a Nucleoside Analog-Resistant Variant of Human Immunodeficiency Virus Type 1 Reverse Transcriptase," <i>J. Virol.</i> 70:4834-4838, The American Society for Microbiology (1996) |
| | AM | <u>5</u> | Drosopoulos, W.C., and Prasad, V.R., "Increased Misincorporation Fidelity Observed for Nucleoside Analog Resistance Mutations M184V and E89G in Human Immunodeficiency Virus Type 1 Reverse Transcriptase Does Not Correlate with the Overall Error Rate Measured In Vitro," <i>J. Virol.</i> 72:4224-4230, The American Society for Microbiology (1998) |
| | AN | <u>5</u> | Eckert, K.A., and Kunkel, T.A., "Fidelity of DNA synthesis catalyzed by human DNA polymerase α and HIV-1 reverse transcriptase: effect of reaction pH," <i>Nucleic Acids Res.</i> 21:5212-5220, Oxford University Press (1993) |
| | AO | <u>5</u> | Eger, B.T., <i>et al.</i> , "Mechanism of DNA Replication Fidelity for Three Mutants of DNA Polymerase I: Klenow fragment KF(exo+), KF(polA5), and KF(exo-)," <i>Biochem.</i> 30:1441-1448, American Chemical Society (1991) |
| | AP | <u>5</u> | Feng, J.Y., and Anderson, K.S., "Mechanistic Studies Examining the Efficiency and Fidelity of DNA Synthesis by the 3TC-Resistant Mutant (184V) of HIV-1 Reverse Transcriptase," <i>Biochemistry</i> 38:9440-9448, The American Chemical Society (July 1999); Published on the web on June 30, 1999. |

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| | AL | <u>6</u> | Finston, W.I. and Champoux, J.J., "RNA-Primed Initiation of Moloney Murine Leukemia Virus Plus Strands by Reverse Transcriptase In Vitro," <i>J. Virology</i> 51:26-33, American Society for Microbiology (1984) |
| | AM | <u>6</u> | Gao, G., and Goff, S.P., "Replication Defect of Moloney Murine Leukemia Virus with a Mutant Reverse Transcriptase That Can Incorporate Ribonucleotides and Deoxyribonucleotides," <i>J. Virol.</i> 72:5905-5911, The American Society for Microbiology (1998) |
| | AN | <u>6</u> | Gerard, G.F., <i>et al.</i> , "cDNA Synthesis by Cloned Moloney Murine Leukemia Virus Reverse Transcriptase Lacking RNase H Activity," <i>Focus</i> 11:66-69, Life Technologies, Inc. (1989) |
| | AO | <u>6</u> | Gerard, G.F., <i>et al.</i> , "Influence on Stability in <i>Escherichia coli</i> of the Carboxy-Terminal Structure of Cloned Moloney Murine Leukemia Virus Reverse Transcriptase," <i>DNA</i> 5:271-279, Mary Ann Liebert, Inc. (1986) |
| | AP | <u>6</u> | Gerard, G., <i>et al.</i> , "cDNA Synthesis by Moloney Murine Leukemia Virus RNase H-Minus Reverse Transcriptase Possessing Full DNA Polymerase Activity," <i>Focus</i> 14:91-93, Life Technologies, Inc. (1992) |

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| | AL | Z | Gerwin, B.I., <i>et al.</i> , "Mutant of B-Tropic Murine Leukemia Virus Synthesizing an Altered Polymerase Molecule," <i>J. Virology</i> 31:741-751, The American Society for Microbiology (1979) |
| | AM | Z | Goff, S.P., "Retroviral Reverse Transcriptase: Synthesis, Structure, and Function," <i>J. Acquired Immune Deficiency Syndrome</i> 3:817-831, Raven Press (1990) |
| | AN | Z | Goff, S.P. and Lobel, L.I., "Mutants of murine leukemia viruses and retroviral replication," <i>Biochimica et Biophysica Acta</i> . 907:93-123, Elsevier Science Publishers B.V. (1987) |
| | AO | Z | Goobar-Larsson, L., <i>et al.</i> , "Disruption of a Salt Bridge between Asp 488 and Lys 465 in HIV-1 Reverse Transcriptase Alters Its Proteolytic Processing and Polymerase Activity," <i>Virology</i> 196:731-738, Academic Press (1993) |
| | AP | Z | Götte, M., <i>et al.</i> , "The M184V Mutation in the Reverse Transcriptase of Human Immunodeficiency Virus Type 1 Impairs Rescue of Chain-Terminated DNA Synthesis," <i>J. Virol.</i> 74:3579-3585, The American Society for Microbiology (April 2000) |

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| | AL | <u>8</u> | Guo, J., et al., "Defects in Primer-Template Binding, Processive DNA Synthesis, and RNase H Activity Associated with Chimeric Reverse Transcriptases Having the Murine Leukemia Virus Polymerase Domain Joined to <i>Escherichia coli</i> RNase H," <i>Biochemistry</i> 34:5018-5029, The American Chemical Society (1995) |
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